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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,834	05/26/2005	Peter C. Harris	07039-386US1	6384
26191 7590 06/19/2007 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER NGUYEN, QUANG	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 06/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/501,834

Applicant(s)

HARRIS ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,8-13,16-19,29-37,40,43-66,78,90,102-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,5,8-13,16-19,29-37,40,43-66,78,90 and 102-104.

### **DETAILED ACTION**

Claims 1-2, 5, 8-13, 16-19, 29-37, 40, 43-66, 78, 90 and 102-104 are pending in the present application, and they are subjected to the following restrictions.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2, 5, 8-13, 16-19, 29-37, 40, 43-51, 60, drawn to an isolated nucleic acid comprising a sequence encoding a fibrocystin polypeptide, a vector and a host cell comprising the same.

Group II, claims 52-59, drawn to a plurality of oligonucleotide primer pairs, wherein each primer pair is 10 to 50 nucleotides in length.

Group III, claim 61, drawn to an antibody having specific binding affinity to a fibrocystin polypeptide.

Group IV, claims 62-66, 78, 90, 102-103, drawn to a method for determining the susceptibility of a subject to autosomal recessive polycystic kidney disease.

Group V, claims 104, drawn to an article of manufacture comprising a substrate containing a population of isolated nucleic acid molecules.

The technical feature linking Groups I-V appears to be a nucleic acid comprising a sequence encoding a fibrocystin polypeptide.

However at the effective filing date of the present application (1/23/02), at least Park et al. (Genomics 57:249-255, 1999; IDS) disclosed 1-Mb BAC/PAC-based physical map that refines the localization of PKHD1, flanked by the markers D6S1714/D6S243 and D6S1024 (see at least the abstract and Figure 1). Additionally, WO 01/75067 A (IDS) and EP 1-104-808 A (IDS) disclosed SEQ ID NO:304 and SEQ ID NO:682, respectively, each of which encodes at least a fibrocystin polypeptide (e.g., containing at least two or more fibrocystin amino acid residues).

Therefore, the technical feature linking the inventions of Groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter as a whole over the prior art. Since according to Rule 13.2 PCT the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT.

Consequently, the claimed subject matter is restricted into the above Groups of Inventions for the following reasons.

The currently claimed subject matter (Inventions of Groups I-V) lacks unity of invention according to Rule 13.1 PCT for the following reasons.

The inventions in Groups I-III and V are directed to different compositions that do not have the same components one from the others. For example, Group I is directed to a nucleic acid comprising a sequence encoding a fibrocystin polypeptide;

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Group II is drawn to a plurality of oligonucleotide primer pairs, wherein each primer pair is 10 to 50 nucleotides in length and it is also noted that an oligonucleotide primer pair is not required to encode a fibrocystin polypeptide; Group III is directed to an antibody having specific binding affinity to a fibrocystin polypeptide, which is structurally and chemically different from a nucleic acid molecule or an oligonucleotide primer; Group V is drawn to an article of manufacture comprising a substrate containing a population of isolated nucleic acid molecules. The invention of Group IV is drawn to a method for determining the susceptibility of a subject to autosomal recessive polycystic kidney disease without requiring the use of any of the compositions in Groups I-III or V for the determination.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**Upon election of either Group I or Group IV**, Applicant is additionally required to elect a single invention. **The claims in either Group I or Group IV comprised of multiple inventions** that are drawn to a plurality of different isolated nucleic acids encoding a fibrocystin polypeptide that have different variations, and a method for determining these nucleotide sequence variants, respectively, as

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encompassed in claims 10, 12, 18,19, 30, 32, 34, 36, 37, 45, 50-51, 66, 78 and 90.

**These nucleotide sequence variants do not share the same “special technical feature” one from the others, nor do they render one obvious from the others, and thus are patentably distinct.** Each unique nucleotide sequence variant can be considered to be a “special technical feature”; and therefore the nucleotide sequence variants encompassed by the aforementioned claims lack the same or corresponding special technical feature.

**Applicant must elect a single invention which directed to a single isolated nucleic acid comprising a sequence encoding a fibrocystin polypeptide from a plurality of isolated nucleic acids as claimed or a method for determining the susceptibility of a subject to autosomal recessive polycystic kidney disease by determining the presence of a single isolated nucleic acid comprising a sequence encoding a fibrocystin polypeptide variant. The applicant must also indicate which claims are readable on the elected invention.**

Note: this group restriction to examination is due to the now very high and undue burden for examining which is caused by the continued exponential increase of size of the sequence databases to be searched, resulting in a corresponding increase in computer search time and examiner's time for reviewing the computer search results. **Therefore, the limited resources of the Office no longer permit examination of multiple distinct sequences** in the composition of Group I, or the method of Group IV as claimed in a single application.

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Note: the non-standard format of this restriction, separating the inventions into multi-invention groups as set forth above was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention which would require a much longer and less clear communication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.**

**Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.**

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

  
QUANG NGUYEN, PH.D.  
PRIMARY EXAMINER